Simplifying the Proposal Process

November 4, 2019

Nikki H. Williams, Senior Research Process Manager
**Clinical Trial?**

**Industry Sponsored Clinical Trials**
Clinical Trial – Research Process Manager (CT-RPM)

*Federal Grant sponsored Clinical Trials will follow the grant process*

**Focus is on Grant Proposals**

- Funding Opportunity Listserv (Email Chelsey Perry to join)
  - [http://med.stanford.edu/rmg/funding.html](http://med.stanford.edu/rmg/funding.html)

- Stanford Research Development Office is now open to assist in the preparation of grants for large multidisciplinary projects and to help early-career assistant professors write grants.
Planning for your submission - Timeline

- Notification to RMG via Proposal Intake Form (PIF)
  - 1 month (30 days) prior to sponsors deadline

- Subcontracts?
  - Notification to RMG via PIF 1.5 months (45 days min.) prior to sponsors deadline
Step 1 – Proposal Notification

Proposal Intake Form (PIF)

*PIF = all “external” funding

**Stanford Internal funding (seed grants) = No PIF/ No RMG involvement

SeRA System

- Standardizes the proposal initiation process:
  - Grants
  - Subcontracts
  - Sponsored research agreements
- Standardizes key information:
  - Program announcement, etc.
- Initiates the budgeting process
- Captures PI approval & Conflict of Interest


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**Step 2 – Are Waivers Needed?**

**Waivers = when contradicts established policy**

1. **Effort** Waivers (1% SOM PI Effort)
2. **Who’s Eligible to be a Principal Investigator?**

Research Policy Handbook 2.14 establishes the policy that **PIship and Co-PIship** on sponsored projects is limited to members of the:
- Academic Council
- Medical Center Line (MCL) Faculty

3. **PI Waivers** needed for:
   - Postdoctoral Scholars
   - Resident/ Clinicians
   - Academic Staff members
   - Instructors

Step 3 - Budget

Proposal Intake Form (PIF)

Waivers?

Budget allocation & allowable cost categories are specified by the announcement/solicitation.

- Federal?
  - *(i.e., Full IDC/Typically budget “direct” costs + IDC)*
- Non-federal?
  - *(i.e., IDC varies, when IDC is zero – 8% ISC charged to PI’s unrestricted account).*
- Industry Contract?
  - *(i.e., Full IDC/Typically negotiate “total” costs)*

If including **subcontracts** – recommended to specify allocation to them.


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Step 4 – Initiate Application

Contact – Nikki (or, corresponding RPM via RMG’s department assignments), will walk through proposal initiation, in real time...

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Cayuse (Application)

eBRAP (Verify)

“Stanford University”

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Step 4 – Initiate Application

Contact – Nikki (or, corresponding RPM via RMG’s department assignments), will walk through proposal initiation, in real time...

- **Proposal Intake Form (PIF)**
- **Waivers?**
- **Budget**
- **Initiate Application**

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Step 4 – Initiate Application

Subcontracts – need to specify to us what they need & timeline? Typical components are:
- Original solicitation, Scope of Work, Budget, & Budget justification

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Proposal Intake Form (PIF)

Waivers?

Budget

Initiate Application
Step 5 – Work on Application

Proposal Intake Form (PIF)

Compliance Panels (IRB, SCRO, APLAC, EH&S)
https://researchcompliance.stanford.edu

Involvement of Human Subjects and/or Animals?
Compliance approvals are “Pending” at time of Application submission

IRB involved at proposal stage?
Yes! All questions involving human subjects in your research should go to IRB.

De-identified data?
Submit a human subjects determination to IRB – IRB will then provide concurrence


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## NIH R01 PROPOSAL CHECKLIST

### BUSINESS & SCIENCE

<table>
<thead>
<tr>
<th>Proposal Documents (Attachments in PDF Format)</th>
<th>Page Limits</th>
<th>Responsibility</th>
<th>Due Dates</th>
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<tbody>
<tr>
<td>BUDGET &amp; BUDGET JUSTIFICATION</td>
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<tr>
<td>Detailed Budget (non-modular)</td>
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<td>PI and RPM</td>
<td>ALL Documents Due</td>
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<td>Scroll to pg 40 of NIH Researc</td>
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<td>Facilities and Other Resources</td>
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<td>PI</td>
<td>Scroll to pg 41 of NIH Researc</td>
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<td><strong>Equipment (if applicable)</strong></td>
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<tr>
<td>Biosketches for Key Persons</td>
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<td>PI</td>
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<td>2.7 Study Timeline</td>
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<td>Starts on pg 112 of NIH Researc</td>
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<td>3.1 Protection of Human Subjects</td>
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<td>PI</td>
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### RESEARCH PLAN

| Specific Aims | 1 page limit | PI | Scroll to pg 81 of NIH Researc |
| Research Strategy (see bottom of table) | 12 page limit | PI | Scroll to pg 81 of NIH Researc |
| **Vertebrate Animals (if applicable)** | No limit | PI | Scroll to pg 87 of NIH Researc |
| **Select Agent Research (if applicable)** | No limit | PI | Scroll to pg 88 of NIH Researc |
| **Multiple PD/PI Leadership Plan (Required - if 2 or more PIs)** | No limit | PI | Scroll to pg 89 of NIH Researc |
| **Consortium/Contractual Agreements (Required - if have sub)** | No limit | PI | Scroll to pg 90 of NIH Researc |
| **Letters of Support (if applicable)** | No limit | PI | Starts on pg 91 of NIH Researc |
| Resource Sharing Plan | No limit | PI | Starts on pg 90 of NIH Researc |
| **Authentication of Key Biological and/or Chemical Resources (if applicable; 1 page suggested)** | No limit | PI | Scroll to pg 91 of NIH Researc |

### SCIENCE

| Bibliography and References | No limit | PI | Scroll to pg 40 of NIH Researc |

## SPONSOR DEADLINE

**NOTES:**

- All science must be submitted in PDF format
- Label attachments to correspond to upload (i.e., Budget Justification, Project Abstract, Project Narrative, Facilities and Other Resources, etc. etc.)
- NIH can now accept project titles up to 200 characters (with spaces)
- NO headers, footers, or page numbers for all documents

### SUBCONTRACT NOTES:

- Subcontracts: Please connect me ASAP to Grants Contact at your collaboration site.
- For projects where you plan to issue a subcontract, please submit your proposal intake form (PIF) 1.5 months in advance (documents and approvals are needed from that institution; and, most institutions have a 2-week mandatory timeline for review, before returning to us).
- Subcontracts: PIs will discuss budget limitations with the subcontract PIs.
- Subcontractor INDIRECT COSTS should not be included when determining if the budget exceeds the total direct cost limit.
Steps 6-7, Review, Feedback, Submit

Proposal Preparation & Submission Timeline
Actions Prior to Due Date

- **30-90 Days**
  - PI Submits Proposal Intake Form (PIF) to RMG.

- **10-30 Days**
  - PI works with RMG to finalize budget. PI prepares application.

- **5 Days**
  - Internal deadline for PI Waivers, budget, & administrative sections.

- **3 Days**
  - Internal deadline for PDRF and final science/proposal.

- **0-3 Days**
  - RMG performs institutional review and submits to sponsor.

Review & Feedback

Submission!

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Questions?